REMARKS

Applicants have carefully reviewed the Office Action mailed December 24, 2008, prior to preparing this response. Currently, claims 1, 5-16, 20, 24-38, and 45 are pending in the application, wherein claims 1, 5-16, 20, 24-38 and 45 have been rejected. Claims 1 and 36 have been amended and claim 37 has been cancelled with this paper. Support for the amendments may be found, for example, at line 16 of page 6 through line 5 of page 7 of the Specification as originally filed, and FIG. 2. No new matter has been added. Favorable consideration of the above amendments and following remarks is respectfully requested.

Claim Rejections under 35 U.S.C. § 112

Claims 1, 5-16, and 37 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Applicants respectfully disagree with the Examiner and traverse the rejection, directing the Examiner's attention to page 4, line 6, through page 6, line 10 of the specification, which discusses the relationship between the polymer jacket 50 and the core wire 20.

Nevertheless, claim 1 has been amended to recite an elongate core wire comprising "a portion formed of a super elastic nickel titanium alloy which is not independently shapeable by forces normally subjected to during a medical procedure." Applicants respectfully believe this amendment overcomes the rejection.

As previously pointed out, it is well known in the art that super-elastic nickel titanium alloy cannot be shaped to a desired form under the forces normally encountered during use as part of a medical device (see Raman et al., U.S. Patent No. 5,368,049, at column 2, lines 57-64). The specification clearly describes the relationship claimed as such that even if a super-elastic nickel titanium alloy with shape memory properties were subjected to the temperature at which those properties are activated, the forces of the shape memory properties would not be sufficient to overcome the stiffness or resistance to changing shape of the polymer jacket. Therefore, the super elastic nickel titanium alloy, as claimed, cannot be shaped independently of the polymer jacket by forces normally subjected to during a medical procedure, i.e., the polymer jacket is required to hold the shape of the super elastic nickel titanium alloy during the medical procedure. Applicants submit that the specification is sufficiently enabling, and respectfully request that the Examiner withdraw the rejection.

Claim Rejections under 35 U.S.C. § 103

Claims 1, 5, 6, 20, 24, 25, 36-38 and 45 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Raman et al. (U.S. Patent No. 5,368,049) in view of Schroeppel (U.S. Patent No. 6,024,764). After careful review, Applicants respectfully traverse this rejection. It is noted that claim 37 has been cancelled with this paper.

Independent claim 1 recites, in part, "an elongate core wire comprising a constant diameter portion and a tapered portion extending distally from the constant diameter portion to a distal end of the core wire...and a polymer jacket comprising a shape memory polymer attached to and surrounding the tapered portion of the core wire formed of a super elastic nickel titanium alloy...the polymer jacket having a length extending proximally from the distal end of the core wire to at least the constant diameter portion."

The Examiner asserts that Raman et al. disclose a formable cladding which surrounds a distal tapered portion of the guidewire. FIG. 1 of Raman et al., reproduced below, illustrates that the cladding 20 is formed on the tip portion 14 of the guidewire, but terminates distally of a constant diameter portion of the guidewire.

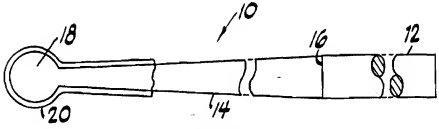

FIG. 1

Turning to the specification of Raman et al., Raman et al. teach a tip portion 14 formed of a superelastic alloy which is joined to the shaft 12 at joint 16. See Raman et al., at column 4, lines 46-51. Applicants direct the Examiner's attention to column 4, lines 63-66, which states that the cladding terminates at a location that leaves "at least a section of superelastic alloy exposed" (emphasis added). Thus, in view of the teachings of Raman et al., the proximal portion of the tapered region does not include the cladding 20. From FIG. 1 of Raman et al., it is

apparent that the cladding 20 does not extend proximally to a constant diameter portion, and Raman et al. expressly teaches away from such a construction.

Schroeppel fails to remedy the noted shortcomings of Raman et al. Therefore, Applicants believe that claim 1 is indeed patentable over the cited combination and request that the rejection be withdrawn.

Accordingly, for at least the reasons cited above and others, claims 5 and 6, which depend from claim 1 and add additional elements thereto, are also believed to be patentable over the cited combination, and Applicants request that the rejections be withdrawn.

Claim 20 recites:

> An intravascular guidewire selectively shapeable by a user and configured for navigation through a vessel lumen of a patient, the guidewire comprising:
> an elongate core wire comprising a distal tip portion formed of a super elastic nickel titanium alloy having an elastic limit; and
> a polymer jacket attached to and surrounding the entire distal tip portion of the core wire such that a substantial portion of the polymer jacket is in contact with the core wire, the polymer jacket comprising a shape memory polymer having an elastic limit, the polymer jacket being more stiff than the distal tip portion of the core wire which it surrounds such that when the distal tip portion is deformed into a curved shape within the elastic limit of the super elastic nickel titanium alloy and beyond the elastic limit of the shape memory polymer, the stiffness of the polymer jacket retains the curved shape imparted on the distal tip portion of the elongate core wire in the vessel lumen of the patient;
> wherein the shape memory polymer is one from a subset of polymers which are characterized by their responsiveness to heating at or above a glass transition temperature of the shape memory polymer in order to independently transform the shape memory polymer between a first shape and a second shape;
> wherein the glass transition temperature of the shape memory polymer is greater than the body temperature of the patient such that the curved shape imparted in the elongate core wire is sustained when the guidewire is navigated through the vessel lumen of the patient.

Applicants respectfully assert a *prima facie* case of obviousness has not been established regarding claim 20. The Examiner asserts that Raman et al. disclose an elongate core wire comprising a distal tip portion formed of a super elastic nickel titanium alloy and a formable cladding surrounding the distal tip portion. The Examiner asserts that "Raman et al. fail to disclose the cladding being a shape memory polymer jacket." Office Action, December 24, 2008, at page 5. The Examiner relies on the teachings of Schroeppel as disclosing a polymer jacket formed of a shape memory polymer, stating that "it would have been obvious…to modify

the cladding as disclosed by Raman et al. to include a shape memory polymer jacket as taught by Schroeppel." Applicants respectfully disagree with the rejection.

Raman et al. teach that the cladding 20 is formed of a metallic material, such as gold, which may be applied to the guidewire tip portion "using any of a variety of well-known electroplating processes." Raman et al., at column 5, lines 27-37. As noted by the Examiner, Raman et al. fail to disclose a polymer jacket comprising a shape memory polymer which is more stiff than a distal tip portion of a core wire formed of a super elastic nickel titanium alloy surrounded by the polymer jacket, such that the stiffness of the polymer jacket retains the curved shape imparted on the distal tip portion of the elongate core wire in a vessel lumen of a patient.

Schroeppel teaches a tubular sleeve 12 for imparting a preselected shape in an implantable tubular device 10 where the tubular sleeve 12 may be made from a heat sensitive shape memory polymer. Schroeppel, at Abstract.

Schroeppel is silent regarding the material of the implantable tubular device 10, and does not teach that the implantable tubular device 10 is formed of a superelastic metal alloy. As shown in FIG. 2 of Schroeppel and described at lines 27-31 of column 4, Schroeppel teaches a plurality of barbs 24 on the tubular sleeve 12 "penetrate slightly into the exterior surface of the implantable tubular device 10," thus seemingly negating any suggestion that Schroeppel teaches that the implantable tubular device 10 may be metallic. Schroeppel does not teach one of skill in the art that the tubular sleeve 12 is of a sufficient stiffness to overcome the resilient forces imparted when a superelastic core wire is bent.

Thus, the teachings of Schroeppel are not sufficient to suggest to one of skill in the art that the heat sensitive shape memory polymer tubular sleeve has a sufficient stiffness to overcome the resilient forces imparted when a superelastic core wire is bent. Without the benefit of Applicants' present application, there is no indication or expectation in the prior art that modifying the cladding 20 of the guidewire of Raman et al. with a shape memory polymer would be sufficient to make a non-shapeable superelastic guidewire selectively shapeable by a user. The Examiner has failed to provide a finding that one of skill in the art would have combined the teachings of Schroeppel with those of Raman et al., and that one of skill in the art would have predicted that the guidewire, as modified, would have functioned as currently claimed.

For at least this reason, it would not be obvious for one of skill in the art to modify the guidewire as disclosed by Raman et al. to include a shape memory polymer as taught by

Schroeppel, as it would not have been predictable that the inclusion of the shape memory polymer would be sufficient to overcome the resiliency of a superelastic core wire to spring back to an original straight shape.

Therefore, Applicants submit that claim 20 is patentable over the cited combination and respectfully request that the Examiner withdraw the rejection. Accordingly, for at least the reasons cited above and others, claims 24, 25 and 38, which depend from claim 20 and add additional elements thereto, are also believed to be patentable over the cited combination, and Applicants request that the rejections be withdrawn.

Independent claim 36 recites, in part, "a core wire having constant diameter portion and a tapered portion extending distally from the constant diameter portion to a distal end of the core wire...and a polymer jacket...attached to and surrounding the entire tapered portion from the distal end to the constant diameter portion of the core wire". As discussed above, Raman et al. do not disclose this configuration and, in fact, teach away from it. Namely, Raman et al. fail to teach the cladding 20 extending to a constant diameter portion of the guidewire. Schroeppel fails to remedy the noted shortcomings of Raman et al. Therefore, Applicants submit that claim 36 is patentable over the cited combination and respectfully request that the Examiner withdraw the rejection.

Claim 45 recites:

> An intravascular guidewire selectively shapeable by a user and configured for navigation through a vessel lumen of a patient, the guidewire comprising:
>
> an elongate core wire including a proximal portion and a distal portion, wherein at least the distal portion is formed of a super elastic metal having an elastic limit and having a resiliency to being substantially straight; and
>
> a polymer jacket attached to and surrounding at least the distal portion of the elongate core wire formed of a super elastic metal, the polymer jacket comprising a shape memory polymer having an elastic limit, the polymer jacket being more stiff than the distal portion of the core wire which it surrounds such that when the distal portion of the core wire and the polymer jacket are deformed into a curved shape within the elastic limit of the super elastic metal and beyond the elastic limit of the shape memory polymer, the stiffness of the polymer jacket overcomes the resiliency of the core wire in order to retain the shape imparted on the distal portion of the elongate core wire in the vessel lumen of the patient;
>
> wherein the shape memory polymer is one from a subset of polymers which are characterized by their responsiveness to heating at or above a glass transition temperature of the shape memory polymer in order to independently transform the shape memory polymer between a first shape and a second shape;

wherein the glass transition temperature of the shape memory polymer is greater than the body temperature of the patient such that the curved shape imparted in the elongate core wire is sustained when the guidewire is navigated through the vessel lumen of the patient.

As discussed above, Raman et al. fail to disclose a polymer jacket comprising a shape memory polymer which is more stiff than a distal tip portion of a core wire formed of a super elastic nickel titanium alloy surrounded by the polymer jacket, such that the stiffness of the polymer jacket retains the curved shape imparted on the distal tip portion of the elongate core wire in a vessel lumen of a patient. Furthermore, the teachings of Schroeppel are not sufficient to suggest to one of skill in the art that the heat sensitive shape memory polymer tubular sleeve of Schroeppel has a sufficient stiffness to overcome the resilient forces imparted when a superelastic core wire is bent. Without the benefit of Applicants' present application, there is no indication or expectation in the prior art that modifying the cladding 20 of the guidewire of Raman et al. with a shape memory polymer would be sufficient to make a non-shapeable superelastic guidewire selectively shapeable by a user. The Examiner has failed to provide a finding that one of skill in the art would have combined the teachings of Schroeppel with those of Raman et al., and that one of skill in the art would have predicted that the guidewire, as modified, would have functioned as currently claimed.

For at least the reasons stated above, Applicants submit that independent claim 45 is patentable over the cited combination, and respectfully request that the Examiner withdraw the rejection.

Claims 7-16 and 26-35 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Raman et al. (U.S. Patent No. 5,368,049) in view of Schroeppel (U.S. Patent No. 6,024,764), and further in view of Takahashi (U.S. Patent No. 6,485,458). After careful review, Applicants respectfully traverse this rejection.

"If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)." (MPEP 2143.03).

For at least the reasons discussed above, independent claims 1 and 20 are believed to be patentable over Raman et al. in view of Schroeppel. Takahashi does not remedy the shortcomings of this combination. Therefore, claims 7-16 and 26-35, which depend from and

add additional elements to claims 1 and 20, respectively, are also believed to be nonobvious, and Applicants request that the rejection be withdrawn.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Stephen Griffin et al.

By their Attorney,

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